Application No.: 10/555,669

AMENDMENTS TO THE CLAIMS

This listing of the claims will replace all prior versions, and listings, of the claims in the application.

In the claims:

- (Currently Amended) A nucleic acid molecule encoding a fusion polypeptide useful as a vaccine composition, which molecule comprises:
 - (a) a first nucleic acid sequence encoding a first polypeptide or peptide that promotes processing via the MHC class I pathway,
 - wherein the first polypeptide or peptide is encoded by
 - (i) SEQ ID NO:9 or by nucleotides 10633-12510 of the Mycobacterium tuberculosis genome set forth in GENBANK Z95324 AL123456; or
 - (ii) SEQ ID NO:10; or
 - (iii) an active C-terminal domain of (i) or (ii);
 - (b) fused in frame with the first nucleic acid sequence, a second nucleic acid sequence encoding a signal peptide; and
 - (c) a third nucleic acid sequence that is linked in frame to said first nucleic acid sequence and that encodes an antigenic polypeptide or peptide which comprises an epitope that binds to a MHC class I protein which epitope is present on, or is crossreactive with, an epitope of a pathogenic organism, cell, or virus.

2.-6. (Canceled)

- 7. (Currently Amended) The nucleic acid molecule of claim [[6]] 1, wherein the virus is a human papilloma virus.
- (Original) The nucleic acid molecule of claim 7, wherein the antigen is an E7
 polypeptide of HPV-16 having the sequence SEQ ID NO: 2, or an antigenic fragment thereof.
- (Original) The nucleic acid molecule of claim 8, wherein the HPV-16 E7 polypeptide is a non-oncogenic mutant or variant of said E7 polypeptide.

B3916936.2 - 2 -

Attorney Docket No.: JHV-050.01

10. (Previously Presented) The non oncogenic mutant of claim 9 wherein the sequence of the

E7 polypeptide differs from SEQ ID NO: 2 by one or more of the following substitutions:

(a) Cvs at position 24 to Glv or Ala.

Application No.: 10/555,669

- (b) Glu at position 26 to Gly or Ala, or
- (c) Cys at position 91 to Gly or Ala.
- 11. (Withdrawn) The nucleic acid molecule of claim 7, wherein the antigen is the E6 polypeptide of HPV-16 having the sequence SEQ ID NO: 4 or an antigenic fragment thereof.
- (Withdrawn) The nucleic acid molecule of claim 11, wherein the HPV-16 E6 polypeptide is a non-oncogenic mutant or variant of said E6 polypeptide.
- 13. (Withdrawn) The non oncogenic mutant of claim 12 wherein the sequence of the E6 polypeptide differs from SEQ ID NO: 4 by one or more of the following substitutions:
 - (a) Cys at position 70 to Gly or Ala
 - (b) Cys at position 113 to Gly or Ala or
 - (c) Ile at position 135 to Thr.
- (Withdrawn) The nucleic acid molecule of claim 1 that is characterized as pNGVL4a-Sig/E7 (detox) /HSP70, and has the sequence SEQ ID NO: 13.
- 15. (Canceled)
- (Previously Presented) An expression vector comprising the nucleic acid molecule of claim 1 operatively linked to
 - (a) a promoter; and
 - optionally, additional regulatory sequences that regulate expression of said nucleic acid in a eukaryotic cell.
- (Withdrawn) An expression vector comprising the nucleic acid molecule of claim 14 operatively linked to
 - (a) a promoter; and

B3916936.2 - 3 -

Application No.: 10/555,669 Attorney Docket No.: JHV-050.01

 optionally, additional regulatory sequences that regulate expression of said nucleic acid in a eukaryotic cell.

- (Previously Presented) The expression vector of claim 16 which comprises plasmid PNGVL4a.
- 19. (Withdrawn) The expression vector of claim 17 which comprises plasmid pNGVL4a.
- (Currently Amended) A pharmaceutical composition capable of inducing or enhancing an antigen-specific immune response, comprising:
 - (a) pharmaceutically and immunologically acceptable excipient in combination with;
 - (b) the nucleic acid molecule of claim 1.
- (Withdrawn-Currently Amended) A pharmaceutical composition capable of inducing-or
 enhaneing-an antigen-specific immune response, comprising:
 - (a) pharmaceutically and immunologically acceptable excipient in combination with;
 - (b) the nucleic acid molecule of claim 14.
- 22. (Currently Amended) A pharmaceutical composition capable of inducing-or-enhancing an antigen-specific immune response, comprising:
 - (a) pharmaceutically and immunologically acceptable excipient in combination with;
 - (b) the expression vector of claim 16.
- (Withdrawn-Currently Amended) A pharmaceutical composition capable of inducing-or enhancing-an antigen-specific immune response, comprising:
 - (a) pharmaceutically and immunologically acceptable excipient in combination with:
 - (b) the expression vector of claim 19.
- 24. (Withdrawn) A method of inducing or enhancing an antigen specific immune response in a subject comprising administering to the subject an effective amount of the pharmaceutical composition of claim 22, thereby inducing or enhancing said response.

B3916936.2 - 4 -

- 25. (Withdrawn) A method of inducing or enhancing an antigen specific immune response in a subject comprising administering to the subject an effective amount of the pharmaceutical composition of claim 44, thereby inducing or enhancing said response.
- 26. (Withdrawn) A method of inducing or enhancing an antigen specific immune response in a subject comprising administering to the subject an effective amount of the pharmaceutical composition of claim 45, thereby inducing or enhancing said response.
- 27. (Withdrawn) A method of inducing or enhancing an antigen specific immune response in a subject comprising administering to the subject an effective amount of the pharmaceutical composition of claim 23, thereby inducing or enhancing said response.
- 28. (Canceled)
- 29. (Withdrawn) The method of claim 24 wherein said subject is a human.
- 30. (Withdrawn) The method of claim 25 wherein said subject is a human.
- 31. (Withdrawn) The method of claim 26 wherein said subject is a human.
- 32. (Withdrawn) The method of claim 27 wherein said subject is a human.
- (Withdrawn) The method of claim 29 wherein said administering is by an intramuscular injection by gene gun administration or by needle-free jet injection.
- 34. (Withdrawn) The method of claim 30 wherein said administering is by an intramuscular injection by gene gun administration or by needle-free jet injection.
- 35. (Withdrawn) The method of claim 31 wherein said administering is by an intramuscular injection by gene gun administration or by needle-free jet injection.
- 36. (Withdrawn) The method of claim 32 wherein said administering is by an intramuscular injection by gene gun administration or by needle-free jet injection.

B3916936.2 - 5 -

- 37. (Withdrawn) A method of inhibiting growth or preventing re-growth of a tumor expressing HPV E7 protein in a subject, comprising administering to said subject an effective amount of a pharmaceutical composition of claim 44, wherein said third nucleic acid sequence encodes one or more epitopes of E7, thereby inhibiting said growth or preventing said re-growth.
- 38. (Withdrawn) A method of inhibiting growth or preventing re-growth of a tumor expressing HPV E6 protein in a subject, comprising administering to said subject an effective amount of a pharmaceutical composition of claim 45, wherein said third nucleic acid sequence encodes one or more epitopes of E6, thereby inhibiting said growth or preventing said re-growth.

(Canceled)

- 40. (Withdrawn) A method of inhibiting growth or preventing re-growth of a tumor expressing HPV E7 protein in a subject, comprising administering to said subject an effective amount of a pharmaceutical composition of claim 23, wherein said third nucleic acid sequence encodes one or more epitopes of E7, thereby inhibiting said growth or preventing said re-growth.
- 41. (Withdrawn) An expression vector comprising the nucleic acid molecule of claim 13 operatively linked to
 - (a) a promoter; and
- (b) optionally, additional regulatory sequences that regulate expression of said nucleic acid in a eukarvotic cell.
- (Withdrawn-Currently Amended) The expression vector of claim 41 which comprises plamid plasmid pNGVL4a.
- (Withdrawn-Currently Amended) A pharmaceutical composition capable of inducing or enhancing an antigen-specific immune response, comprising:
 - (a) pharmaceutically and immunologically acceptable excipient in combination with;
 - (b) the nucleic acid molecule of claim 13.
- 44. (Withdrawn-Currently Amended) A pharmaceutical composition capable of inducing of enhancing an antigen-specific immune response, comprising:

B3916936.2 - 6 -

Application No.: 10/555,669 Attorney Docket No.: JHV-050.01

(a) pharmaceutically and immunologically acceptable excipient in combination with;

- (b) the expression vector of claim 17.
- 45. (Withdrawn-Currently Amended) A pharmaceutical composition capable of inducing or enhancing an antigen-specific immune response, comprising:
 - (a) pharmaceutically and immunologically acceptable excipient in combination with;
 - (b) the expression vector of claim 41.

B3916936.2 - 7 -